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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,041	03/14/2000	Daniel R. Soppet	PF178D2	8342

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/525,041	SOPPET ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *21-24,26-37,46-49, 51-63,72-76,78-89,98-101,103-115 and 124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *27,30-34,36,37,53,56-60,62,63,89,105,107-112,114 and 115* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 21-24,26,28,29,35,46-49,51,52,54,55,61,72-76,78-88,98-101,103,104,106,113 and 124.

1. The Amendment filed April 7, 2004 in response to the Office Action of January 7, 2004 is acknowledged and has been entered. Previously pending claims 38-45, 50, 64-71, 90-97, 116-124 have been canceled and claims 37 and 115 have been amended. Claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-101, 103-115 124 are currently under prosecution.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejection are maintained:

Claim Rejections - 35 USC § 112

4. Claims 73-76, 78-87, 98-101 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed January 7, 2004, Section 4, pages 2-4.

Applicant argues that (a) a suitable deposit for patent purposes was previously submitted as evidenced by the teaching of the specification at page 5 last paragraph which teaches that "isolated nucleic acids which encode for the mature polypeptide having the deduced amino acid sequence of SEQ ID NO:2 or for the mature polypeptide encoded by the cDNA of the clone(s) deposited as ATCC Deposit No. 97129", hence the specification teaches that the invention was deposited on April 28, 1995. Further, Applicant makes a statement, in the Response, on the availability of the Deposit wherein the name and address of the depository is disclosed as well as the date of deposit and a statement that all restrictions on the availability to the public of ATCC 97129 will be irrevocably removed upon the grant of a patent based on the instant application, (b) one would understand that the polynucleotide encoding SEQ ID NO:2 and the cDNA clone in the ATCC 97129 are one and the same and that the specification provides a nexus

between ATCC 97129 and SEQ ID NO:2. Applicant points to the specification at page 6, second and third paragraphs, page 7, second through fourth full paragraphs and page 10, first full paragraph.

The argument has been considered but has not been found persuasive because (a') the amendments and the statement do not meet the requirements of 35 USC 112, first paragraph since Applicant does not include the required statement that the deposit will be replaced if viable samples cannot be dispensed by the depository (b') a review of page 6, second and third paragraphs, page 7, second through fourth full paragraphs and page 10, first full paragraph provides support for the following, (1) the coding sequence which encodes the mature polypeptides may be identical to the coding sequence, SEQ ID NO:1 or that of the deposited clone(s), the polynucleotides which encode for the mature polypeptide, SEQ ID NO:2 or for the mature polypeptide encoded by the deposited cDNA may include..... (page 6), the present invention includes polynucleotides encoding the same mature polypeptide shown as SEQ ID NO:2 or the same mature polypeptide encoded by the cDNA of the deposited clones, the polynucleotides may have a coding sequence which is a naturally occurring allelic variant of the coding sequence SEQID NO:1 or of the coding sequence of the deposited clones, the present invention also includes polynucleotides wherein the coding sequence for the mature polypeptides may be fused in the same reading frame to a polynucleotide sequence which aids in expression and secretion of a polypeptide from a host cell (page 7), the present invention is directed to polynucleotides having .....identity to polynucleotides which encode the polypeptide of SEQ ID NO:2 as well as fragments thereof. The cited paragraphs provide no nexus whatsoever between ATCC 97129 and SEQ ID

NO:2. In every single instance, the polynucleotide encoding SEQ ID NO:2 is recited as an alternative to ATCC 97129. There is simply no suggestion that they are one and the same and thus no one would understand that the polynucleotide encoding SEQ ID NO:2 and the cDNA clone in the ATCC 97129 are one and the same or that the specification provides a nexus between ATCC 97129 and SEQ ID NO:2. The argument has been considered but has not been found persuasive and the rejection is maintained.

5. Claims 29, 55, 81 remain rejected under 35 USC 112, second paragraph for the reasons previously set forth in the paper mailed January 7, 2004, Section 5, pages 4-5.

Applicant argues that (a) the term chimeric antibodies was routinely used and understood by those of ordinary skill in the art and Applicant submits three publications describing chimeric antibodies to support the argument, (b) the pending claims do not allow for any domain to be substituted because the claimed chimeras are limited to antibodies that specifically bind polypeptides of the invention.

The argument has been considered but has not been found persuasive because (a') a review of the references reveals that the chimeric antibody of Baier et al is drawn to antibodies comprising immunogenic determinants of HIV-1 gp120 and antibody Fab fragments reactive with surface structures of APCs, the chimeric antibody of Poon et al is drawn to domain-switched immunoglobulins with identical anti-dansyl variable domains, employing as parent antibodies a human IgM and a mouse IgG2b, the chimeric antibody of Maloney et al is drawn to an antibody consisting of human IgG1 constant regions and variable regions form the murine anti-CD20 antibody IDEC-

2B8. Applicant has clearly demonstrated with the submission of these references that there is no art recognized definition of a chimeric antibody since all of the antibodies are different in their composition and their construction and given this information, the metes and bounds of the claimed invention cannot be determined, (b') contrary to Applicant's argument, Examiner did not suggest that any domain can be substituted, but rather, as specifically recited by Applicant, Examiner stated that any domain of the antibody is substituted by corresponding regions or residues of human antibodies, once again, the metes and bounds of the claimed chimeric antibodies cannot be determined, The arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

6. Claims 21-24, 26, 28, 35, 46-49, 51-52, 54, 61, 73-76, 78, 80, 87, 98-101, 103-104, 106, 113, 124 remain rejected under 35 USC 102(a) and 102(e) and claim 72 is rejected under 35 USC 102 (a) and 102 (e) for the reasons previously set forth in the paper mailed January 7, 2004, Section 7, pages 5-7.

As drawn to claim 72, it is obvious that claim 72 was not previously included in the instant rejection due to an inadvertent typographical error engendered in part by the numerous claims under prosecution, given Examiner's statements in the previous action. As Applicant correctly points out, claim 72 is an independent claim. Further, the claim clearly reads on polyclonal antibodies encompassed by the prior art reference of record. Examiner apologizes for any inconvenience. In any case, the issue remains the same, in the absence of a limitation drawn to a monoclonal antibody, the claim is not allowable.

Applicant argues that (a') the '169 patent does not contemplate polypeptides with the 30% identity of the instantly claimed polypeptide to SEQ ID NO:7, (b) the presently pending claims are drawn to antibodies that specifically bind Colon Specific Protein of the present invention and species othologs, but not to paralogs and antibodies that cross-react with human PAP of the '169 and Colon Specific Protein of the present invention are not encompassed by the presently pending claims, (c) Applicant points to Boehringer Mannheim Biochemicals, Inc., 1994 Catalog page 20 as an example of an antibody described as "specifically" binding orthologous proteins in different species, suggesting that an antibody that binds to two different proteins that are not orthologous would not be an antibody that specifically binds.

The arguments have been considered but have not been found persuasive because (a') Applicant is arguing limitations not recited in the claims as currently constituted, the instant claims are drawn to antibodies, (b')(c') Applicant is arguing limitations not recited in the claims as currently constituted since the claims are simply drawn to antibodies that bind specifically. Solely for Applicant's information it is noted that Gelboin (Pharmacological Review, 1993, 45:413-453) specifically teaches that the specificity of antibody binding resides in the precise ability to recognize and bind a specific epitope on the surface of an antigen and that an antibody that recognizes an epitope that is present in more than one form of the antigen will bind all of those forms containing the common epitope (p. 416, para 2), thus specifically bind to each of the forms that shares a common epitope. It is clear, for the reasons previously set forth, that a subset of the polyclonal antibodies of the '169 patent will specifically bind to SEQ ID NO:2. The

arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

7. Claims 21-24, 26, 28, 35, 46-49, 51-52, 54, 61, 73-76, 78, 80, 87, 98-101, 103-104, 106, 113 and 124 remain rejected under the 35 USC 103 and claim 72 is rejected under 35 USC 102 (a) and 102 (e) for the reasons previously set forth in the paper mailed January 7, 2004, Section 8 this, pages 7-10.

As drawn to claim 72, it is obvious that claim 72 was not previously included in the instant rejection due to an inadvertent typographical error engendered in part by the numerous claims under prosecution, given Examiner's statements in the previous action. As Applicant correctly points out, claim 72 is an independent claim. Further, the claim clearly reads on polyclonal antibodies encompassed by the prior art reference of record. Examiner apologizes for any inconvenience. In any case, the issue remains the same, in the absence of a limitation drawn to a monoclonal antibody, the claim is not allowable.

Applicant argues that (a) since US Patent No. 5, 436, 169 does not comprise an anticipatory reference for the reasons provided above this reference may not properly be combined with Bartoli et al. to allege obviousness, (b) Applicant reiterates arguments drawn to specific binding Colon Specific Protein and species orthologs.

The arguments have been considered but have not been found persuasive because (a') US Patent No. 5,436,169 is an anticipatory reference for the obviousness, (b') this argument has previously been considered and has not been found persuasive for the reasons set forth above.

Claim Objections

8. Objection to Claims 27, 30-34, 36-37, 53, 56-60, 62-63, 89, 105, 107-112, 114-115 remain for the reasons previously set forth in the paper mailed January 7, 2004, Section 9 this, page 10.

Applicant argues that (a) there is no logical legal distinction for allowing claims drawn to monoclonal antibodies but denying claims drawn to polyclonal antibodies, (b) applicant reiterates arguments drawn to cross reactivity.

The arguments have been considered but have not been found persuasive because (a') the legal distinction is clear to one of ordinary skill because it is known that polyclonal antibodies produced against an antigen will bind to numerous epitopes on that antigen. Thus a subset of polyclonal antibodies produced against the antigen of the reference would be expected to bind to the seven amino acids that are shared by both the instantly claimed antigen and the reference antigen. However, monoclonal antibodies are known for their exquisite specificity and there would be no motivation for producing a monoclonal antibody against the single shared epitope, (b') the arguments are not persuasive for the reasons set forth previously and above.

9. No claims allowed.

10. All other objections and rejections set forth in the paper mailed January 7, 2004 are hereby withdrawn.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS

FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 872-9306.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
July 9, 2004